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Congressional Record dated Tuesday, September 23, 1997
Senate Section

Measure Debated by JEFFORDS (R-VT) and 3 others -- S. 830
UNANIMOUS-CONSENT AGREEMENT [CR page S-9759, 247 lines]

Attributed to JEFFORDS (R-VT)

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I have a unanimous-consent request which I
will offer.

I ask unanimous consent that immediately following the cloture vote with respect to S. 830, if invoked, there be only the following time remaining in the following fashion: 4 hours equally divided between the chairman and the ranking minority member or their designee for use during today's session only; 4 hours equally divided between the chairman and the ranking minority member or their designee for use during the session of the Senate on Wednesday, September 24, beginning at noon.

I further ask, notwithstanding rule XXII, that following the conclusion or yielding back of time, the Senate proceed to vote on S. 830, as amended, without further action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 1137

The PRESIDING OFFICER. Under the previous agreement, we now have 20 minutes equally divided on the Harkin amendment numbered 1137, 10 minutes under the control of the Senator from Iowa and 10 minutes under the control of the Senator from Tennessee.

The Senator from Iowa is recognized.

Mr. HARKIN. I yield myself 5 minutes.

Mr. President, there are many positive provisions in this bill that I am pleased to support. However, I am disappointed that an essential element has not been included in this bill. A major goal of FDA reform is to ensure that the public has access to medical innovations without compromising public

safety. But the multimillion-dollar cost of obtaining FDA approval often excludes from the review process all medical therapies not promoted by major corporations, those that are nonpatentable or low cost.

Very few sponsors of alternative medicines and treatments have the resources to go through this process. Unfortunately, this means that millions of Americans are denied access to important alternative medicines and treatments every day. In committee, I proposed and withdrew an amendment that would improve the access to medical care. It was called the Access to Medical Treatment Act. It was introduced this spring by Senator Daschle, cosponsored by the majority leader, Senator Lott, Senators Hatch, Inouye, myself, and many others. It would allow greater freedom of choice and increased access in the realm of alternative medical treatments, while preventing abuses of unscrupulous practitioners.

However, it appears that we may not be ready to move on this important consumer reform. Mr. President, while we may not be ready for this, we cannot delay in moving to assure and improve and expand rigorous scientific review of alternative and complementary therapies. That is the purpose of my amendment.

Mr. President, increasingly Americans are turning to alternative medicine. A study done by Harvard University showed, in 1990, American consumers spent over \$14 billion on these practices. In that year, there were over 425 million visits to alternative practitioners, more than visits to conventional practitioners.

In light of that, in 1992, the Congress passed a bill setting up the Office of Alternative Medicine at the National Institutes of Health. We now have 4 1/2 years' experience with that office operating. It has done some good things, but it has been severely hampered by the fact that it must go through the entire process at NIH, through the institutes at NIH, for its peer review

and for its grant-making authority.

The amendment I have before the Senate now would simply change the status of the Office of Alternative Medicine from an office under the Director to a center for complementary and alternative medicine. It would not be an institute but a center. As such, that center could set up a peer review process and make its own grants.

Now, why is that important? Mr. President, every year since we established the office, we put in the legislation that the office's responsibility was to investigate and validate treatments, practices and medicines. That has been in there every year--to investigate and validate--because what we want is scientific analysis done of these treatments. Now, I have always heard, "There are a lot of quacks out there practicing alternative medicine." While that may be true, there are a lot of good people out there doing good things with alternative medicine. We need the review and the science to let us know what is good and what is working.

I asked the Director of NIH a few months ago, who was in my office, how many treatments, or practices, or medicines they had investigated and validated since 1992. I was met with a deafening silence. The answer is, none. Yet, next year we are putting \$13 million into the Office of Alternative Medicine. One might rightly ask, where is it going? What is happening?

So the purpose of my amendment was to set up a center to elevate its status so that that center could do its own peer review and have its own grant-making authority. That way, we can cut through and save a lot of money and save a lot of time, without in any way compromising rigorous scientific review. That is what this amendment does. It also incorporates within that center the Office of Dietary Supplements, which was also set up at NIH, to bring the two of them together in a new center which would provide more

independence, assure economies of scale and efficiencies without in any way denigrating good scientific research. That is the purpose of the amendment.


Now, I understand that the Senator from Tennessee is going to raise a point of order that this amendment is not germane. Under the rules of cloture, I admit that it is not germane. That doesn't mean it is not important. It is very important. It is critically important. It should be passed.

Mr. President, I understand my 5 minutes are up. I yield 2 minutes to one of my chief cosponsors, the Senator from Maryland.

The PRESIDING OFFICER. The Senator from Maryland is recognized.

Ms. MIKULSKI. Mr. President, I rise to cosponsor Senator Harkin's amendment to establish the Center of Alternative Medicine. I helped him establish the Office of Alternative Medicine in 1993 at NIH. Why did I do that? One, because I want everyone who is sick in the United States of America to have access to all possible means of treatment that are safe and have efficacy. At the same time, I wanted to prevent quackery. I also was aware of the Harvard study by a Dr. Eisenberg that said one out of three Americans was using alternative or complementary medicine, but we were not aware of scientific investigation to establish its efficacy or its safety. Yet, many of us have enjoyed those practices.

Some years ago, I had some very severe illnesses. Western medicine was of limited utility for me and I turned to acupuncture. Acupuncture helped me get well and has helped me stay well. I am pleased about that. But there are many other modalities out there being utilized by the American consumer. I want to make sure they are safe. I want to make sure they have efficacy. I want NIH to investigate it, and then I want them to validate it. I believe there is merit in this.



I am puzzled why NIH wants to continually try to submerge this Office of Alternative or Complementary Medicine. The hallmark of NIH is to have an open mind and to pursue scientific investigation. I believe Senator Harkin is on the right track. Though this amendment might not be germane, it is certainly relevant to the American people. If we don't find a way to move it on this bill, let's explore other ways.

I yield back such time as I might have.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. I have a unanimous-consent request, Mr. President.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I ask unanimous consent that following debate and disposition of the Harkin amendment, Senator Murray be recognized for 5 minutes to offer her amendment No. 1161, and that following her remarks, her amendment be agreed to.

I further ask unanimous consent that the following amendments be called up, considered en bloc and agreed to: A Jeffords amendment No. 1174; a Jeffords amendment No. 1175; a Kennedy amendment No. 1152; a Wellstone amendment No. 1156, and Senator DeWine's amendment No. 1136, as modified in the amendment I send to the desk.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Reserving the right to object, Mr. President. I was hard-pressed to hear the numbers. Was amendment No. 1131 included in that?

Mr. JEFFORDS. There are no nongermane amendments in the unanimous-consent request.

Mr. HARKIN. I appreciate that.

The PRESIDING OFFICER. Without objection, it is so ordered.

Who yields time?

Mr. FRIST. Mr. President, I yield myself 9 minutes.

Mr. President, I rise today to respond to my colleague from Iowa with regard to an amendment to the Food and Drug Administration [FDA] reform bill, to establish a new national center for complementary and alternative medicine at the National Institutes of Health [NIH].

Again, remember the debate today and the past several days, and maybe through tomorrow, is on the FDA. Yet, we have introduced an amendment on another agency--the NIH. I oppose the offering of this proposal as an amendment to the FDA bill for that very reason.

Comments have been made earlier about the importance of complementary and alternative medicine to the public and to this country, the importance of science, and the importance of peer review--all of which I support. I have been in the field of medicine, in a broad sense, for the last 20 years. I have been involved in many medical fields, including a great part of which has been designated as alternative therapies--at least initially, because when I first started doing lung transplants, very few had been done in the history of this country before. Therefore, I, as a scientist, a medical

professional, and a U.S. Senator, do feel that alternative medicine and complementary medicine is vitally important to the health and the well-being of Americans and people throughout the world.

What I do oppose, however, is dealing with this issue of elevating an office to the level of a center when most of our colleagues do not even know what a center in the NIH really means. What are the responsibilities of a center? What are the authorities? What is the difference between an office and a center and an institute? As I talk to my colleagues, they do not know. Why? Because we have not addressed the issue in the appropriate environment--that is, through the committee structure.

I am the chairman of the Subcommittee on Public Health and Safety, which oversees the reauthorization of the NIH. We are, right now, looking at the reauthorization of the NIH. We have held two hearings in the past examining how you set biomedical and medical research priorities. It is a process where we have people come in and testify, and we discuss and debate back and forth. This amendment, as proposed by the Senator from Iowa, has not been taken through that process. It is being brought to the floor on a bill that does not have anything to do with the NIH, but rather the FDA bill. Therefore, I do believe it is not germane.

I believe we should not be placing NIH authorizing legislation on an FDA bill. Rather, the more appropriate process would be to take it through the committee structure. I should also add, for the benefit of my colleagues, most of whom have not addressed this issue at all because it has not been through the committee process, that no legislative bill to establish a center of alternative medicine has been introduced into the Senate. Therefore, a bill has not been referred to the appropriate committee, it has not been vetted, it has not had hearings. There has been no formal debate. This would create a huge center within the NIH without that debate. Therefore, I object to bypassing this process, again, with a tremendous amount of respect for

alternative medicine.

My colleague from Iowa is a senior member of the subcommittee, and he and I have had the discussion that we do need to look at the appropriate role for alternative medicine at the NIH. We have scheduled a hearing in early October. It has been mentioned on the floor of the Senate that one of the panels should address the issue of alternative medicine.

We have a 4-year history with the Office of Alternative Medicine. Let's debate and look at the results of that history. Let's see the results of peer review and see what advances have been made.

The issue of whether to elevate an office to a center--again, as I talked to my colleagues over the last few weeks about taking an office at the NIH and elevating it to a center--is one that I think we need to discuss, but not today on the FDA bill, not over the course of a few minutes, but look at it through the appropriate hearing process. What does it mean to elevate an office to center status? What is a center at the NIH? I hope my colleagues ask themselves right now, do I really know what a center at the NIH is? Most will say no. The role of the current Office of Alternative Medicine, the office--as outlined by the Senator from Iowa, my colleague, who basically defined what the office is --is to coordinate and foster the conduct and support of alternative medicine research at the NIH. Right now, the office provides a central focus for a research area that is germane to all NIH components. In other words, the office can work with all the various institutes.

I understand that the majority of complementary and alternative research is performed and supported by those 24 centers and institutes and divisions within the NIH, and it is integrated within the scientific research portfolio of each of those institutes. My colleague is arguing--and he may be right, and that is why we need to discuss it--that we must consider alternative

medicine being a center in and of itself. But that would mean that the scientists and researchers who are responsible for broad areas of science may not have the opportunity to integrate alternative medicine into their respective research portfolios as they do today. It needs to be discussed. It needs to be debated in the appropriate forum.

I recognize that the Senator from Iowa has concerns about whether the current approach is working or not. Again, I look forward, through our reauthorizing committee, to the Subcommittee on Public Health and Safety, on which he serves, to address this very issue.

I do know that when you elevate an entity like an office to an institute or to center status, the scientific potential of the field should be sufficiently demonstrated so that the new institute or center can support a thriving intramural and extramural program. Are we at that point today? I do not know. I daresay that most of my colleagues have not studied this specific issue yet.

I will have to say that as I have reached out to people, many others in the scientific community have raised concerns about establishing a new center at the NIH. Let me read to you a portion of a letter sent to me from the Association of the American Medical Colleges expressing their concerns:

This is the AAMC, Association of the American Medical Colleges:

Any change in the organizational structure of the NIH of this magnitude raises significant scientific and administrative questions. . . .

Further, the AAMC believes all members of the research community should have the opportunity to address these issues in a full and public manner during a hearing conducted by the subcommittee.

Mr. President, I ask unanimous consent that the letter by the AAMC be printed in the Record.

There being no objection, the letter was ordered to be printed in the Record, as follows:

Measure Debated by FRIST (R-TN) and HARKIN (D-IA) -- S. 830
Food and Drug Administration Modernization and Accountability Act of
1997 [CR page S-9761, 65 lines]

Attributed to FRIST (R-TN)

Mr. FRIST. Mr. President, raising the Office of Alternative Medicine to a center at NIH greatly increases its statutory authority. Has the field of alternative medicine demonstrated that track record to date? Again, let's review these issues in the committee process. The Office of Alternative Medicine today clearly does not have the organizational structure or the necessary budget to support this proposal--creating a national center for complementary and alternative medicine would require setting up a whole new administrative structure and a whole new research infrastructure to support this activity.

Are we ready for that today? Possibly.

Let's ask the scientists around the country. Let's have alternative medicine researchers come forward and testify. Let's ask the National Institutes of Health. Before we go out and create another center, which again is a new entity, we need to look at the proposal about its administration, and about how it will be paid for.

Again, the watchwords today are "consolidation and coordination," not proliferation.

Mr. President, I would like to reserve the remaining minute of my time.

The PRESIDING OFFICER. Who yields time?

Mr. HARKIN. Mr. President, I have a couple of minutes.

The PRESIDING OFFICER. The Senator from Iowa has 2 minutes and 45 seconds.

Mr. HARKIN. Mr. President, I will respond to my friend from Tennessee who made the argument. He said it would create a huge center at NIH. I am sorry. The Office of Alternative Medicine has 14 employees, the last count I had, and its budget next year is \$13 million out of \$13 billion at NIH. That is one-tenth of 1 percent. Huge? I beg to differ.

There are only two changes under this amendment. It provides that it could make grants, that it could do its own grants, and could have peer review. That is the only difference. We are not creating anything new and huge. It is up to the Congress to decide later on if they want to expand it or not. I am just changing its status.

Also, Mr. President, I want to say that if it were not for this point of order this amendment would pass. The cosponsors are Senators Hatch, Daschle, Craig, Mikulski, Lugar, Specter, Grassley, Durbin, Wellstone, Moseley-Braun, and a number of others. I am not going to read them all.

This amendment would pass, if the point of order were not raised.

The Senator says it should go through the committee structure, that we have

not had hearings, and stuff. I say in all friendship--and he is a great friend of mine, the Senator from Tennessee--that just a couple of weeks ago the Senator voted on the Gorton amendment that cut out title I--vocational education, safe and drug-free schools, education technology, bilingual education--knocked it all out. And, yet, we never had one hearing on it. It never went through our committee, of which the Senator and I both sit. We never had any hearings on that. Yet the Senator from Tennessee says fine. He stepped up and voted to abolish all of those without going" through the hearing process.

But I would say to my friend from Tennessee, you want more testimony. Look at the Record. Our subcommittee on both the appropriations side and on the authorizing side have had hearing after hearing after hearing on this. We have had all kinds of testimony come in.

But the most compelling testimony, Mr. President, for this amendment is that more and more Americans are using alternative practices in medicines than they are using with mainstream doctors. They are spending billions of dollars a year. At last count it was over \$13 billion in 1 year.

It is up to us to make sure that we do the adequate scientific research to find out what alternative medicines are working and what are not.

That is why this center is needed. It may not be germane to this bill. But I will tell you. It is needed. It is drastically needed today--not next year or 2 years or 3 years from now. We have had enough testimony basically from the American people.

Mr. President, I ask unanimous consent to have printed in the Record a letter from a number of organizations supporting the amendment.

There being no objection, the material was ordered to be printed in the

Record, as follows:
